



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5  
77 WEST JACKSON BOULEVARD  
CHICAGO, IL 60604-3590

DEC 14 2011

REPLY TO THE ATTENTION OF:

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Joseph E. Simon  
Director, Environment, Health, Safety and Energy  
Abbott Laboratories  
Department 05G2, Building M1  
1401 Sheridan Road  
North Chicago, Illinois 60064-6299

Re: In the Matter of: Abbott Laboratories - North Chicago, Illinois - CAFO  
Docket No. CAA-05-2012-0004

Dear Mr. Simon:

Enclosed is a file-stamped Consent Agreement and Final Order (CAFO) which addresses Abbott Laboratories' (Abbott's) penalty liability stemming from the Notice of Violation/Finding of Violation issued to Abbott on January 24, 2011. As indicated by the filing stamp on its first page, we filed the CAFO with the Regional Hearing Clerk on DEC 14 2011.

Pursuant to paragraph 31 of the CAFO, Abbott Laboratories must pay the civil penalty within 30 days of DEC 14 2011. Your check must display the case name, case Docket No. CAA-05-2012-0004 and the billing document number 2751203A005.

Please direct any question regarding this case to Thomas Martin, Associate Regional Counsel, at 312-886-4273.

Sincerely,

 for  
Brent  
Marable

Brent Marable  
Chief  
Air Enforcement and Compliance Assurance Section (IL/IN)

Enclosure

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DEC 14 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5

REGIONAL HEARING CLERK  
U.S. ENVIRONMENTAL  
PROTECTION AGENCY

In the Matter of:	)	Docket No. <u>CAA-05-2012-0004</u>
	)	
Abbott Laboratories	)	Proceeding to Assess a Civil Penalty
North Chicago, Illinois.	)	Under Section 113(d) of the Clean Air Act,
	)	42 U.S.C. § 7413(d)
Respondent.	)	
<hr/>		

**Consent Agreement and Final Order**

**Preliminary Statement**

1. This is an administrative action commenced and concluded under Section 113(d) of the Clean Air Act (the Act), 42 U.S.C. § 7413(d), and Sections 22.1(a)(2), 22.13(b) and 22.18(b)(2) and (3) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules), as codified at 40 C.F.R. Part 22.
2. Complainant is the Director of the Air and Radiation Division, U.S. Environmental Protection Agency, Region 5.
3. Respondent is Abbott Laboratories, a corporation doing business in Illinois.
4. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be commenced and concluded simultaneously by the issuance of a consent agreement and final order (CAFO). 40 C.F.R. § 22.13(b).
5. The parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their interest and in the public interest.
6. Respondent consents to the assessment of the civil penalty specified in this CAFO and to the terms of this CAFO.

### **Jurisdiction and Waiver of Right to Hearing**

7. Respondent admits the jurisdictional allegations in this CAFO and neither admits nor denies the factual allegations in this CAFO.

8. Respondent waives its right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO, and its right to appeal this CAFO.

### **Statutory and Regulatory Background**

9. Under Section 112 of the Act, 42 U.S.C. § 7412, EPA promulgated the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production (Subpart GGG) at 40 C.F.R. §§ 63.1250 through 63.1261.

10. The NESHAP General Provisions (Subpart A) are found at 40 C.F.R. §§ 63.1 through 63.16.

11. The NESHAP for Pharmaceuticals Production applies to operations that manufacture a pharmaceutical product, are a major source, and process, use or produce hazardous air pollutants (HAPs).

12. The NESHAP for Pharmaceuticals Production, at 40 C.F.R. § 63.1254(a)(3)(i), requires that for existing sources, "...uncontrolled HAP emissions from a process vent must be reduced by 98 percent ..."

13. The NESHAP General Provisions, at 40 C.F.R. § 63.6(e)(1)(i), state that, "At all times, including periods of startup, shutdown, and malfunction, the owner or operator must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions."

14. Title V of the CAA, 42 U.S.C. §§ 7661-7661f, establishes an operating permit program for certain major sources of air emissions. Pursuant to Section 502(b) of the CAA,

42 U.S.C. § 7661a(b), on July 21, 1992, EPA promulgated regulations implementing the requirements of Title V and establishing the minimum elements of a permit program to be administered by any state or local air pollution control agency. See 57 Fed. Reg. 32250 (July 21, 1992). These regulations are codified at 40 C.F.R. Part 70.

15. The Illinois Environmental Protection Agency (IEPA) issued Title V Permit, Application No.: 96010011 (Title V permit), to Abbott on June 27, 2000.

16. Section 5.2.6 of Abbott's Title V permit states: "This stationary source, as defined in 40 CFR § 63.1250, is subject to 40 CFR Part 63, Subpart GGG, National Emission Standards for Pharmaceuticals Production."

17. The Administrator of EPA (the Administrator) may assess a civil penalty of up to \$37,500 per day of violation up to a total of \$295,000 for violations that occurred after January 12, 2009, pursuant to Section 113(d)(1) of the Act, 42 U.S.C. § 7413(d)(1), and 40 C.F.R. Part 19.

18. Section 113(d)(1) of the Act limits the Administrator's authority to matters where the first alleged date of violation occurred no more than 12 months prior to initiation of the administrative action, except where the Administrator and Attorney General of the United States jointly determine that a matter involving a longer period of violation is appropriate for an administrative penalty action.

19. The Administrator and the Attorney General of the United States, each through their respective delegates, have determined jointly that an administrative penalty action is appropriate for the period of violations alleged in this CAFO.

### **Factual Allegations and Alleged Violations**

20. Abbott owns and operates a pharmaceutical manufacturing plant at 1401 Sheridan Road in North Chicago, Illinois (facility).

21. At its facility, Abbott manufactures bulk pharmaceutical active ingredients by fermentation and chemical synthesis; is a major source of carbon monoxide, nitrogen oxides, particulate matter less than 10 micrometers in diameter, sulfur dioxide, volatile organic material and HAP emissions; and processes, uses or produces HAPs. Thus, Abbott is subject to the NESHAP for Pharmaceuticals Production.

22. Dichloromethane (also known as methylene chloride) is a HAP that is used at the Abbott facility in a pharmaceutical manufacturing process that produces antibiotics, such as erythromycin, via a fermentation batch process.

23. Abbott controls dichloromethane emissions from its pharmaceutical manufacturing process with a carbon bed adsorption system. This is a three-bed system that typically operates with one bed in adsorption mode, a second bed in regeneration/cool-down mode and the third bed in standby mode.

24. On February 1, 2010, Abbott submitted a malfunction letter to EPA, Region 5 and the IEPA in accordance with 40 C.F.R. § 63.1260(i)(2) and 40 C.F.R. § 63.10(d)(5)(ii).

25. On February 3, 2010, EPA, Region 5 received the malfunction letter from Abbott regarding its facility, which identified a malfunction that occurred at the regeneration steaming temperature continuous monitor, along with subsequent malfunctions of the adsorption timer and alarm system.

26. Abbott's malfunction letter reported that as a result of the identified malfunctions, on January 23 and 24, 2010, its facility released 3,000 pounds (1,331 kg) of dichloromethane as

excess emissions in a 16.8-hour period. Dichloromethane was released at a rate of approximately 179 pounds/hour.

27. On January 24, 2011, EPA issued to Abbott a Notice of Violation/Finding of Violation (NOV/FOV) alleging that Abbott violated the NESHAP for Pharmaceuticals Production because dichloromethane emissions from a process vent were not reduced by 98 percent on January 23 and 24, 2010, in accordance with 40 C.F.R. § 63.1254(a)(3)(i).

28. In addition to the above-mentioned allegation, during the malfunction that occurred at the automatic control system for carbon bed adsorption system operation on January 23 and 24, 2010, EPA alleges that Abbott did not operate and maintain its pharmaceutical manufacturing process emission sources and carbon bed adsorption system in a manner consistent with safety and good air pollution control practices for minimizing emissions in accordance with 40 C.F.R. § 63.6(e)(1)(i) because Abbott failed to:

- a. Check the status of timer alarm, fault and shutdown conditions along with any other alarms during each shift so as to prevent excess emissions;
- b. Comply with its startup, shutdown and malfunction plan (SSM Plan) by not purging emissions to the two other adsorbers to prevent the use of the malfunctioning adsorber until it was operating properly;
- c. Comply with its SSM Plan by not taking actions to shut down the pharmaceutical manufacturing process equipment when there was a malfunction and excess emissions were being released to the atmosphere; and
- d. Have an adequate alarm system in place to provide effective communication to staff to prevent excess emissions.

EPA finds that failure to follow good air pollution control practices resulted in a release of 3,000 pounds of dichloromethane in a 16.8-hour period.

29. On February 24, 2011, EPA and Abbott held a conference to discuss the January 24, 2011 NOV/FOV.

**Civil Penalty**

30. Based on analysis of the factors specified in Section 113(e) of the Act, 42 U.S.C. § 7413(e), the facts of this case and in consideration of Respondent's degree of cooperation, return to compliance and an agreement to carry out a Supplemental Environmental Project (SEP), Complainant has determined that an appropriate civil penalty to settle this action is \$10,155.

31. Within 30 days after the effective date of this CAFO, Respondent must pay the \$10,155 civil penalty by sending a cashier's or certified check via certified mail, payable to "Treasurer, United States of America," to:

U.S. EPA  
Fines and Penalties  
Cincinnati Finance Center  
P.O. Box 979077  
St. Louis, Missouri 63197-9000

The check must note 'Abbott Laboratories - North Chicago, Illinois - CAFO,' the docket number of this CAFO and the billing document number.

32. Respondent must send a notice of payment that states 'Abbott Laboratories - North Chicago, Illinois - CAFO,' the docket number of this CAFO and the billing document number to the Compliance Tracker, Air Enforcement and Compliance Assurance Branch and to Thomas Martin at the following addresses when it pays the civil penalty:

Attn: Compliance Tracker (AE-17J)  
Air Enforcement and Compliance Assurance Branch  
Air and Radiation Division  
U.S. EPA, Region 5  
77 W. Jackson Boulevard  
Chicago, Illinois 60604

Thomas Martin (C-14J)  
Office of Regional Counsel  
U.S. EPA, Region 5  
77 W. Jackson Boulevard  
Chicago, IL 60604

33. This civil penalty is not deductible for federal tax purposes.

34. If Respondent does not pay timely the civil penalty, or any stipulated penalties due under paragraph 48, below, EPA may bring an action to collect any unpaid portion of the penalty with interest, handling charges, nonpayment penalties and the United States enforcement expenses for the collection action under Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.

35. Pursuant to 31 C.F.R. § 901.9, Respondent must pay the following on any amount overdue under this CAFO. Interest will accrue on any overdue amount from the date payment was due at a rate established by the Secretary of the Treasury. Respondent must pay a \$15 handling charge each month that any portion of the penalty is more than 30 days past due. In addition, Respondent must pay a quarterly nonpayment penalty each quarter during which the assessed penalty is overdue according to Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). This nonpayment penalty will be 10 percent of the aggregate amount of the outstanding penalties and nonpayment penalties accrued from the beginning of the quarter.

**Supplemental Environmental Project**

36. Respondent must complete a SEP designed to mitigate the public health effects that may have been caused by the dichloromethane (also known as methylene chloride) emissions release that occurred on January 23 and 24, 2010 at the Respondent's facility in North Chicago, Illinois.



37. At its Abbott Park, Illinois facility, Respondent shall complete a SEP that entails replacing approximately 300 lighting fixtures with more energy efficient fixtures, including installation of light-emitting diode (LED) bulbs. The old lighting fixtures and components must be removed and disposed of in an environmentally proper manner (guidelines for handling fluorescent light ballasts containing polychlorinated biphenyls (PCBs), if found at Respondent's plant, are found here: <http://www.epa.gov/epawaste/hazard/tsd/pcbs/pubs/ballasts.htm>). The new lighting fixtures must utilize approximately half the energy consumption of the old fixtures.

38. This Energy Efficient Lighting SEP will occur at Respondent's Abbott Park plant instead of at its North Chicago plant because the North Chicago plant is scheduled to cease fermentation operations by the end of 2014. The Abbott Park plant is approximately five miles west of the North Chicago plant.

39. Abbott shall complete this Energy Efficient Lighting SEP by March 31, 2012. The SEP shall be continually operated at the facility following its installation.

40. Abbott shall complete this Energy Efficient Lighting SEP at a cost of no less than \$185,000.

41. Abbott's implementation of this Energy Efficient Lighting SEP will increase its Abbott Park plant's energy efficiency and reduce its energy needs, and, as a result, the coal-fired power plant providing energy to Respondent's Abbott Park plant will emit less carbon dioxide, sulfur dioxide, nitrogen, particulate matter and mercury.

42. EPA may inspect the facility at any time to monitor Respondent's compliance with this CAFO's Energy Efficient Lighting SEP requirements.

43. Respondent must submit an Energy Efficient Lighting SEP completion report to EPA by May 31, 2012. This report must contain the following information:

- a. Detailed description of the SEP as completed;
- b. Description of any operating problems and the actions taken to correct the problems;
- c. Itemized cost of goods and services used to complete the SEP, documented by copies of invoices, purchase orders or canceled checks that specifically identify and itemize the individual cost of the goods and services;
- d. Certification that Respondent has completed the SEP in compliance with this CAFO; and
- e. Description of the environmental and public health benefits resulting from the SEP (quantify the benefits and pollution reductions, if feasible).

44. Respondent must submit all notices and reports required by this CAFO by first class mail to the Compliance Tracker in the Air Enforcement and Compliance Assurance Branch at the address provided in paragraph 32, above.

45. In each report that Respondent submits as provided by this CAFO, it must certify that the report is true and complete by including the following statement signed by one of its officers:

I certify that I am familiar with the information in this document and that, based on my inquiry of those individuals responsible for obtaining the information, it is true and complete to the best of my knowledge. I know that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.

46. Following receipt of the Energy Efficient Lighting SEP completion report described in paragraph 43, above, EPA must notify Respondent in writing that:

- a. It has satisfactorily completed the SEP and the SEP report;
- b. There are deficiencies in the SEP as completed or in the SEP report and EPA will give Respondent 30 days to correct the deficiencies; or
- c. It has not satisfactorily completed the SEP or the SEP report and EPA will seek stipulated penalties under paragraph 48.

47. If EPA exercises option b, above, Respondent may object in writing to the deficiency notice within 10 days of receiving the notice. The parties will have 30 days from EPA's receipt of Respondent's objection to reach an agreement. If the parties cannot reach an agreement, EPA will give Respondent a written decision on its objection. Respondent will comply with any requirement that EPA imposes in its decision. If Respondent does not complete the Energy Efficient Lighting SEP as required by EPA's decision, Respondent will pay stipulated penalties to the United States under paragraph 48, below.

48. If Respondent violates any requirement of this CAFO relating to the Energy Efficient Lighting SEP, Respondent must pay stipulated penalties to the United States as follows:

- a. Except as provided in subparagraph b, below, if Respondent did not complete the SEP satisfactorily according to the requirements of this CAFO, including the schedule in paragraph 39, Respondent must pay a penalty of \$23,000.
- b. If Respondent did not complete the SEP satisfactorily, but EPA determines that Respondent made good faith and timely efforts to complete the SEP and certified, with supporting documents, that it spent at least 90 percent of the amount set forth in paragraph 40, Respondent will not be liable for any stipulated penalty under subparagraph a, above.
- c. If Respondent completed the SEP satisfactorily, but spent less than 90 percent of the amount set forth in paragraph 40, Respondent must pay a penalty of \$3,000.
- d. If Respondent did not submit timely the SEP completion report required by paragraph 43, Respondent must pay penalties in the following amounts for each day after the report was due until it submits the report:

<u>Penalty per violation per day</u>	<u>Period of violation</u>
\$250	1 <sup>st</sup> through 14 <sup>th</sup> day
\$500	15 <sup>th</sup> through 30 <sup>th</sup> day
\$1,000	31 <sup>st</sup> day and beyond

49. EPA's determinations of whether Respondent satisfactorily completed the Energy Efficient Lighting SEP and whether Respondent made good faith and timely efforts to complete the SEP will bind Respondent.

50. Respondent must pay any stipulated penalties within 15 days of receiving EPA's written demand for the penalties. Respondent will use the method of payment specified in paragraph 31, above, and will pay interest, handling charges and nonpayment penalties on any overdue amounts.

51. Any public statement that Respondent makes referring to the Energy Efficient Lighting SEP must include the following language, "Abbott Laboratories undertook this project under the settlement of the United States Environmental Protection Agency's enforcement action against Abbott Laboratories for violations of the National Emission Standards for Hazardous Air Pollutants for Pharmaceuticals Production."

52. If an event occurs which causes or may cause a delay in completing the Energy Efficient Lighting SEP as required by this CAFO:

- a. Respondent must notify EPA in writing within 10 days after learning of an event which caused or may cause a delay in completing the SEP. The notice must describe the anticipated length of the delay, its cause(s), Respondent's past and proposed actions to prevent or minimize the delay and a schedule to carry out those actions. Respondent must take all reasonable actions to avoid or minimize any delay. If Respondent fails to notify EPA according to this paragraph, Respondent will not receive an extension of time to complete the SEP.
- b. If the parties agree that circumstances beyond the control of Respondent caused or may cause a delay in completing the SEP, the parties will stipulate to an extension of time no longer than the period of delay.
- c. If EPA does not agree that circumstances beyond the control of Respondent caused or may cause a delay in completing the SEP, EPA will notify Respondent in writing of its decision and any delays in completing the SEP will not be excused.

- d. Respondent has the burden of proving that circumstances beyond its control caused or may cause a delay in completing the SEP. Increased costs for completing the SEP will not be a basis for an extension of time under subparagraph b, above. Delay in achieving an interim step will not necessarily justify or excuse delay in achieving subsequent steps.

53. Respondent certifies that:

I certify that Abbott is not a party to any open financial assistance transaction that is funding or could be used to fund the same activity as the Energy Efficient Lighting SEP. I further certify that, to the best of my knowledge and belief after reasonable inquiry, that there is no such open federal financial transaction that is funding or could be used to fund the same activity as the Energy Efficient Lighting SEP, nor has the same activity been described in an unsuccessful federal financial assistance transaction proposal submitted to EPA within two years of the date of this settlement (unless the project was barred from funding as statutorily ineligible). For the purposes of this certification, the term "open federal financial assistance transaction" refers to a grant, cooperative agreement, loan, federally-guaranteed loan guarantee or other mechanism for providing federal financial assistance whose performance period has not yet expired.

54. For federal income tax purposes, Respondent will neither capitalize into inventory or basis, nor deduct any cost or expenditures incurred in performing the Energy Efficient Lighting SEP.

**General Provisions**

55. This CAFO resolves only Respondent's liability for federal civil penalties for the violations alleged in the CAFO.

56. This CAFO does not affect the rights of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violation of law.

57. This CAFO does not affect Respondent's responsibility to comply with the Act and other applicable federal, state and local laws. Except as provided in paragraph 55, above, compliance with this CAFO will not be a defense to any actions subsequently commenced pursuant to federal laws administered by EPA.

58. Respondent certifies that it is complying fully with the NESHAP for Pharmaceuticals Production.

59. This CAFO constitutes an "enforcement response" as that term is used in EPA's Clean Air Act Stationary Source Civil Penalty Policy to determine Respondent's "full compliance history" under Section 113(e) of the Act, 42 U.S.C. § 7413(e).

60. The terms of this CAFO bind Respondent, its successors and assigns.

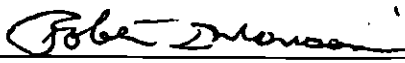
61. Each person signing this consent agreement certifies that he or she has the authority to sign for the party whom he or she represents and to bind that party to its terms.

62. Each party agrees to bear its own costs and attorney's fees in this action.

63. This CAFO constitutes that entire agreement between the parties.


**Abbott Laboratories, Respondent**

9/29/11  
Date

  
Robert D. Morrison  
Divisional Vice President, Environmental, Health,  
Safety and Energy  
Abbott Laboratories

**United States Environmental Protection Agency, Complainant**

9/30/11  
Date

  
Cheryl L. Newton  
Director  
Air and Radiation Division  
U.S. Environmental Protection Agency  
Region 5

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DEC 14 2011

**Consent Agreement and Final Order**

**In the Matter of: Abbott Laboratories**

**Docket No. CAA-05-2012-0004 *24***

**REGIONAL HEARING CLERK  
U.S. ENVIRONMENTAL  
PROTECTION AGENCY**

**Final Order**

This Consent Agreement and Final Order, as agreed to by parties, shall become effective immediately upon filing with the Regional Hearing Clerk. This Final Order concludes this proceeding pursuant to 40 C.F.R. §§ 22.18 and 22.31. IT IS SO ORDERED.

12/12/11  
Date



Susan Hedman  
Regional Administrator  
U.S. Environmental Protection Agency  
Region 5

**Consent Agreement and Final Order**  
**In the Matter of: Abbott Laboratories**  
**Docket No. CAA-05-2012-0004**

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DEC 14 2011

REGIONAL HEARING CLERK  
U.S. ENVIRONMENTAL  
PROTECTION AGENCY

**Certificate of Service**

I certify that I filed the original and one copy of the Consent Agreement and Final Order (CAFO), Docket No. CAA-05-2012-0004, with the Regional Hearing Clerk (E-19J), United States Environmental Protection Agency, Region 5, 77 W. Jackson Boulevard, Chicago, Illinois 60604, and that I mailed a second original copy by first-class, postage prepaid, certified mail, return receipt requested, by placing it in the custody of the United States Postal Service addressed as follows:

Joseph E. Simon  
Director, Environment, Health, Safety and Energy  
Abbott Laboratories  
Department 05G2, Building M1  
1401 Sheridan Road  
North Chicago, Illinois 60064-6299

I certify that I mailed a copy of the CAFO by first-class mail, addressed as follows:

Steven J. Ziesmann  
Senior Counsel  
Abbott Laboratories  
Legal Regulatory and Compliance  
Department 32RA, Building AP6A-2  
100 Abbott Park Road  
Abbott Park, Illinois 60064

and

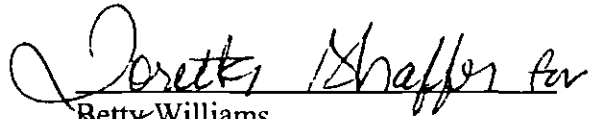
Ray Pilapil, Chief  
Bureau of Air  
Compliance and Enforcement Section  
Illinois Environmental Protection Agency  
1021 North Grand Avenue East  
Springfield, Illinois 62702



I also certify that I delivered a copy of the CAFO by intra-office mail, addressed as follows:

Marcy Toney  
Regional Judicial Officer  
U.S. Environmental Protection Agency, Region 5  
77 W. Jackson Boulevard/Mail Code C-14J  
Chicago, Illinois 60604

On the 14<sup>th</sup> day of December 2011.



Betty Williams  
Administrative Program Assistant  
Planning and Administration Section

CERTIFIED MAIL RECEIPT NUMBER:

70091680 0000 7673 8798

CERTIFIED MAIL RECEIPT NUMBER:

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